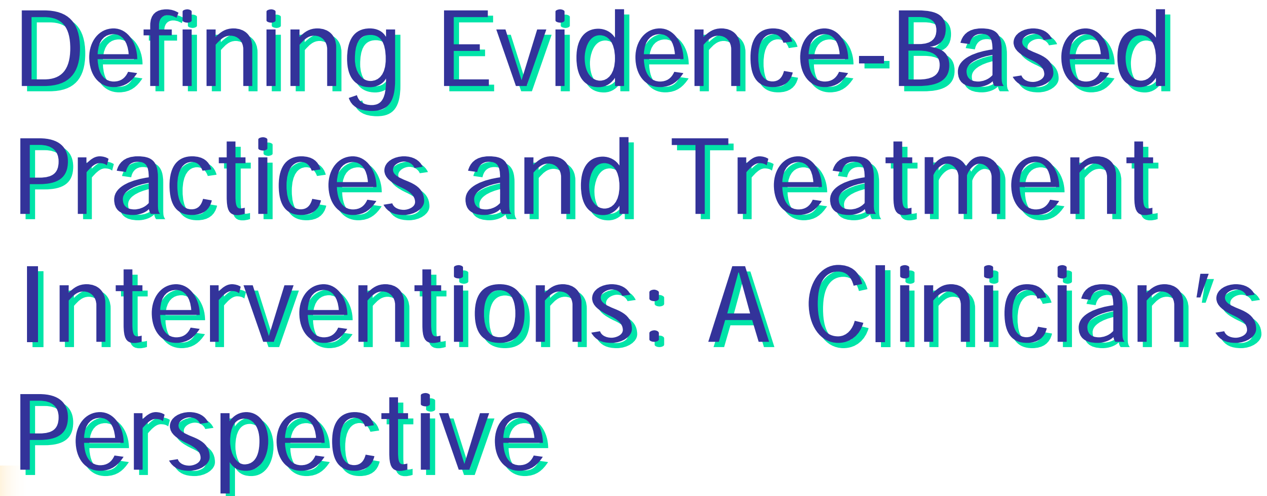

Defining Evidence-Based Practices and Treatment Interventions: A Clinician's Perspective

NIDA BLENDING CONFERENCE – Oct 16, 2006
Seattle, Washington

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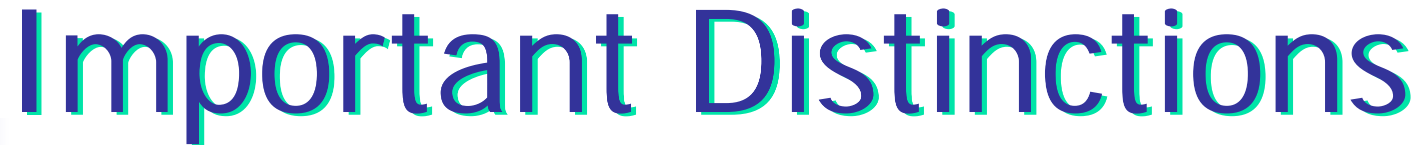
What do we need to know to improve care?



Important Distinctions

- Evidence-based **principles** and practices guide system development
  - Example: care that is appropriately comprehensive and continuous over time will produce better outcomes
- Evidence-based **treatment interventions** are important elements in the overall picture. They are not a substitute for overall adequate care.

Clinician Questions?

- Should we admit people who are still drinking and using?
- Should they see a psychiatrist while they are still drinking/using?
- Should we discharge them if they don't comply with our exacting program requirements?
- Should we discharge them if they drink/use?

Policies and Practices Not Supported by Research

- Requiring abstinence as a condition of access to substance abuse or mental health treatment
- Denying access to AOD treatment programs for people on prescribed medications
- Arbitrary prohibitions against the use of certain prescribed medications
- Discharging clients for alcohol/drug use

Evidence Based Principles

Principles and practices are derived from different types of research:

- Correlational findings:
  - Retention improves outcomes; we need to engage people, not discharge prematurely
  - Pts in methadone maintenance show a higher reduction in morbidity and mortality and improvement in psychosocial indicators than heroin users outside treatment or not on MAT.
- Longitudinal and epidemiological studies
  - Addicts/alcoholics are a heterogeneous population, not a particular personality type
  - Addiction behaves like other chronic disorders

Important Naturalistic, Longitudinal Studies

- Natural history of alcoholism:

  Vaillant, G. E. (1995). *The Natural History of Alcoholism Revisited*. Cambridge, Mass.: Harvard University Press

- Natural history of heroin addiction

  Hser, Y. I., Hoffman, V., Grella, C. E., & Anglin, M. D. (2001). A 33-year follow-up of narcotics addicts. *Arch Gen Psychiatry, 58* (5), 503-508

- Drug Abuse Treatment Outcome Studies (DATOS) – NIDA (Fletcher), NDRI (Hubbard), TCU (Simpson), UCLA (Anglin) (www.datos.org)

Reasons for Field-based Treatment Outcome Studies

- Effectiveness in “real world settings”
- Funding decisions by policy-makers
- Public information & support
- Test impact of clinical advancements
- Changes occur over time in --
  - Types or trends of patient drug use
  - Treatment services & resources

(www.datos.org)

Specific psychosocial interventions are usually investigated in random assignment studies using manualized treatments in carefully controlled trials. Samples and settings are homogeneous and treatment is standardized. Specific procedures assure fidelity to the model.

Random Assignment Controlled Trials (RCT's)

Gold standard for pharmacological and many psychosocial interventions

Examples with strong efficacy:

- Cognitive behavioral therapy
- Motivational interviewing
- Behavioral marital therapy
- Community reinforcement approach
- Relapse prevention
- Social skills training

(see Miller et al, 2005)

Are RCT's Over-rated?

QUERI

RCT

Mark Willenbring MD
(ASAM 2006)

Issues with RCT's

- Is the research question an appropriate question?
  - Example: CBT A compared with CBT B, vs CBT A compared with TAU
  - How does it compare with what my program does now?
- Are the treatment effects modest or robust?
- What is the cost to achieve and maintain the intervention? Are the results worth it?

- RCT designs have limitations and are not always best for investigating key aspects of behavior change process:
  - What influences people to seek and engage in treatment?
  - How do these self-selection processes and contextual influences contribute to the change process?

(Tucker & Roth, Addiction, 2006)

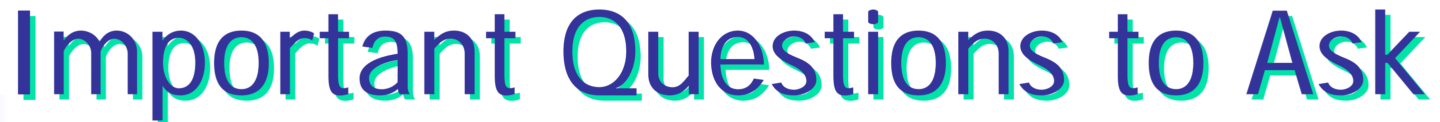
- RCT's commonly use restricted, unrepresentative samples
- Alternative methods: multivariate, longitudinal, and observational studies
- Investigate pathways and mechanisms of change, with or without treatment
- Public health perspective: a modestly efficacious treatment that is adopted and diffused easily can have much greater impact at the population level

(Tucker & Roth, Addiction, 2006)

Can we assume that interventions with documented efficacy will be effective in the community if we only implement them correctly?

- Assumption that effectiveness research naturally flows from efficacy research is faulty.
- The tight controls of efficacy studies limit their generalizability.
- Focus more on intervention reach, adoption, implementation, and maintenance.
- Published studies should include more info on external validity.

(Glasgow et al, AJPH, 2003)



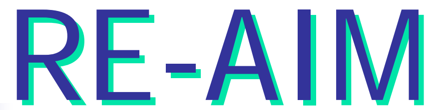
Important Questions to Ask

What are the characteristics of interventions that can:

1. Reach large numbers of people, especially those who can most benefit
2. Be broadly adopted by different settings
3. Be consistently implemented by different staff with moderate training and expertise
4. Produce replicable and long lasting effects (with minimal negative impact) at reasonable costs.

(Glasgow et al, AJPH, 2003)

Public Health Perspective: RE-AIM



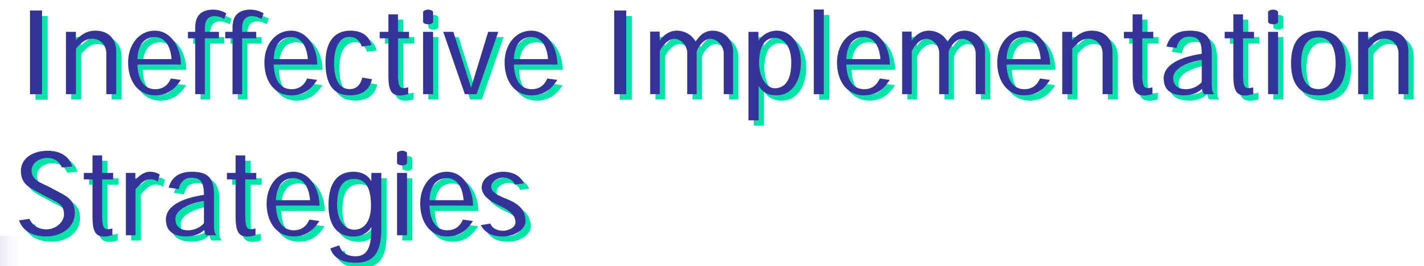
The translatability and public health impact of interventions is best evaluated by examining all five of the following dimensions:

- **<u>R</u>**each into the target population
- **<u>E</u>**fficacy or effectiveness
- **<u>A</u>**doption by target settings or institutions
- **<u>I</u>**mplementation—consistency of delivery of intervention
- **<u>M</u>**aintenance of intervention effects in individuals and populations over time.

(www.re-aim.org)

Barriers to Implementation in the Substance Abuse Treatment System

A Preview



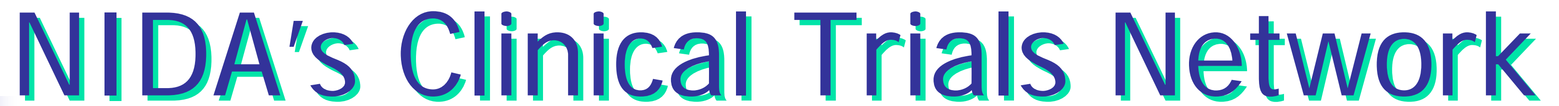
"…experimental studies indicate that dissemination of information does not result in positive implementation outcomes (changes in practitioner behavior) or intervention outcomes (benefits to consumers)"

(Fixsen et al, 2005)

- Presenting information; instructions
- Demonstrations (live or taped)
- Practice key skills; behavior rehearsal
- Feedback on Practice
- Other reinforcing strategies; peer and organizational support

(Fixsen et al, 2005)

Activities and Challenges
at the Federal Level



NIDA's Clinical Trials Network

- Mission: to improve the quality of drug abuse treatment using science as the vehicle
- 17 regional centers; over 100 treatment programs throughout the US
- Conduct multi-site trials to determine effectiveness in broad range of settings and populations
- **Ensure transfer of research results**

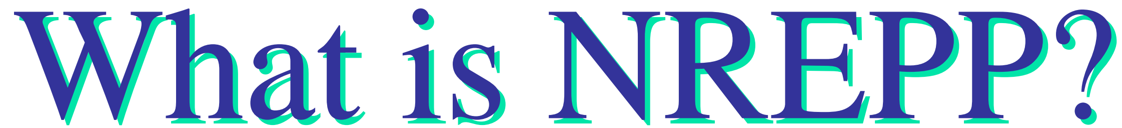
The ATTC Network focuses on six areas of emphasis for improving addiction treatment:

- Enhancing cultural appropriateness
- Developing and disseminating tools
- Building a better workforce
- Advancing knowledge adoption
- Ongoing assessment and improvement
- Forging partnerships

(www.nattc.org)

Addiction Technology Transfer Centers (ATTC's)

- Is NIDA authorized to do some of the on-the-ground skill practice and other activities, or does this go to CSAT?
- How will we address issues of organizational culture and community support?
- Are we going to have silos that undermine effective action, like the difficulties we still face with co-occurring disorders?



- National Registry of Effective Programs and Practices
  - formerly the National Registry of Effective Prevention Programs
  - Part of science-to-service initiative
- Began in 1998 within SAMHSA's CSAP as a voluntary system for identifying & promoting interventions that are:
  - Well implemented
  - Thoroughly evaluated
  - Produce consistent positive and replicable results
  - Able to assist in dissemination and training efforts

- NREPP becomes a signature SAMHSA activity/product
- SAMHSA becomes widely known as the place to:
  - Identify effective, evidence-based programs and practices – including successful coalition efforts
  - Receive – or be linked with - “implementation assistance” to implement a model program/practice
  - Seek – or be linked with - “development assistance” to build a program or practice evidence-base

Evolution of NREPP

- NREPP was expanded to include treatment (c. 2002)
- Well-respected, evidence-based treatment providers did not pass muster
- Federal Register notice inviting public comment on plans for expansion and use (August 26, 2005)
- Changes announced, based on public comments (March 14, 2006)
- Federal Register on SAMHSA's priorities for 2007 (June 30, 2006)

- NREPP as proposed was an attempt to shape policy based on incomplete science, imposed on an inadequate infrastructure
- Beware the premise that treatment will improve if confined to interventions for which a certain type of evidence is available.
- Effectiveness studies are absent or inadequate for interventions supported by efficacy trials.

Concerns Expressed During Public Comment Period - II

- Evidence-based practices are important contributions to treatment but must be recognized as part of a larger scenario.
- Treatment providers need to be at the table when decisions are made about the criteria and process for evaluating practices. Participating in stakeholder meetings is not enough.
- Treatment is a multi-faceted process that includes a number of interventions, many of which are individualized.

Minimum Review Requirements (June 30, 2006)

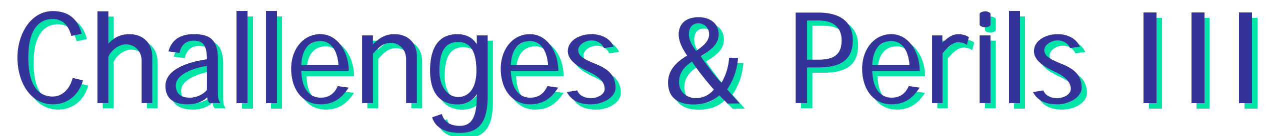
- The intervention demonstrates one or more positive changes (outcomes) in mental health and/or substance use behavior among individuals, communities or populations.
- Intervention results have been published in a peer-reviewed publication or documented in a comprehensive evaluation report
- Documentation (e.g., manuals, process guides, tools, training materials) of the intervention and its proper implementation is available to the public to facilitate dissemination

(Federal Register/Vol 71, No. 126/Friday, June 30, 2006/Notices)

Perils

- Funders adopting a “pick from this list” approach
- Policy makers misinterpreting research findings; drawing inappropriate conclusions
  - Example: buprenorphine (“transfer methadone pts to BPN and taper them off”)
- Impostors
  - Claim to be based on science, but present multiple anecdotes with no comparison or control groups as “proof.”

- How to make cultural adaptations and maintain the treatment effects?
- What is the tradeoff between fidelity and the need to adapt interventions for specific populations?
- Achieving fidelity takes labor intensive supervision, and most states don't fund supervision. Cheers for Florida. Others?



Challenges & Perils III

- What about the huge gaps in the research literature (s.g., group interventions, therapist variables)?
- The existing infrastructure cannot handle the expectation for data collection. No mention of funding for this at the program level.
- High training fees for “proven” practices

- Clearly defined evidence-based principles and practices are a great resource
- Implementation is a big challenge
- Don't stop thinking!

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